

REMARKS

Claim Rejections – 35 U.S.C. §103

Claims 1, 2, 4, 6, 10-16, 21, 31, 32 and 34-36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,699,248 to Jackson in view of U.S. Patent No. 4,274,401 to Miskew, claims 3 and 5 stand rejected as being unpatentable over Jackson in view of Miskew and in further view of U.S. Patent No. 6,238,396 to Lombardo, and claims 7, 8, 17, 18, 33, 37 and 38 stand rejected as being unpatentable over Jackson in view of Miskew and in further view of U.S. Patent No. 5,980,523 to Jackson.

The seminal case directed to application of 35 U.S.C. §103 is Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). From this case, four familiar factual inquiries have resulted. The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. (See Manual of Patent Examining Procedure §2141). From these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness. For at least the following reasons, it is respectfully submitted that a *prima facie* case of obviousness has not been established in this case.

Declaration of Prior Invention in the United States Under 37 C.F.R. §1.131

The Applicant previously submitted a Declaration of Prior Invention under 37 C.F.R. §1.131 (hereafter the “Declaration”) to remove U.S. Patent No. 6,699,248 to Jackson as prior art to the subject application in a Supplemental Response filed with the U.S. Patent and Trademark Office on January 12, 2009. The Declaration included a copy of an Invention Disclosure that includes drawings and a description of the Invention to evidence conception and reduction to practice of the Invention prior to May 9, 2002, the purported effective filing date of Jackson. Despite these materials, the outstanding final Office Action asserts that the Declaration was insufficient to establish a reduction to practice prior to the effective date of Jackson. Notably, it is asserted that “[t]he notebook drawings are insufficient to establish an actual reduction to practice of the invention.” (See Office Action, page 2). Citing In re Asahi/American Inc., 68 F.3d 442, 37 U.S.P.Q.2d 1204 (Fed. Cir. 1995), the Office Action further asserts that “[i]n

general, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose” and that “[t]his evidence may be provided in the form of photographs, coupled with articles and/or a technical report.” (See Office Action, page 2). As will be established below, the assertion that the Declaration and supporting exhibits were insufficient to remove Jackson as prior art to the subject application is believed to be in error.

As an initial matter, the Applicant notes that the Office Action asserts that evidence of actual reduction to practice may (emphasis added) be provided in the form of photographs, articles and/or technical reports. The use of the word “may” in this context clearly implies that establishing actual reduction to practice by photographs, articles and/or technical reports is permissive or possible, but not mandatory (i.e., other items can be used to establish an actual reduction to practice). Indeed, it is respectfully submitted that this notion is commensurate with the requirements of 37 C.F.R. §1.131(b) and the holding of In re Asahi/American Inc. With regard to 37 C.F.R. §1.131(b), this regulation does not enumerate any particular requirement for photographs to support an actual reduction to practice, but instead generally instructs that “[o]riginal exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained.” It is respectfully submitted that the Invention Disclosure clearly qualifies as an original exhibit of drawings or records as set forth in 37 C.F.R. §1.131(b).

Additionally, In re Asahi/American Inc. does not establish or require that photographs, articles and/or technical reports must be submitted to establish an actual reduction to practice. Moreover, In re Asahi/American Inc. generally dealt with issues related to the need of a showing, independent of a showing that a claimed invention actually existed, that the claimed invention worked for its intended purposed. More particularly, in In re Asahi/American Inc., Asahi submitted a declaration during reexamination to show reduction to practice of the claimed invention before the filing date of a cited reference. In contrast to the subject application, Asahi did not submit a formalized invention disclosure with drawings and other evidence of actual reduction to practice. Rather, Asahi relied on photographs and descriptions included in two trade publications as part of commercial offerings of the claimed invention. (See In re Asahi, 37 U.S.P.Q.2d 1204 at 1205). The Board of Patent Appeals and Interferences found that Asahi’s declaration did not show that the claimed restraint coupling worked for its intended purpose, and

thus held that the declaration was insufficient to prove reduction to practice. The Court in In re Asahi/American Inc. disagreed however, noting in reliance on Sachs v. Wadsworth, 48 F.2d 928, 929, 9 U.S.P.Q. 252, 253 (C.C.P.A. 1931), that “there are some devices so simple that a mere construction of them is all that is necessary to constitute reduction to practice.” (In re Asahi, 37 U.S.P.Q.2d 1204 at 1206). The Court ultimately concluded that the photograph, coupled with the §1.131 declaration, established that the claimed restraint coupling was constructed, and that since it was such a simple device, its mere construction was all that was necessary to establish reduction to practice (i.e., an independent showing that the restraint coupling worked for its intended purpose was not necessary). (Id. at 1207-1208). Thus, In re Asahi/American Inc. does not establish a requirement that photographs, articles and/or technical reports must be submitted to evidence actual reduction to practice. Rather, it indicates that these materials were sufficient to establish a reduction to practice based on the facts of that case.

As indicated above, In re Asahi/American Inc. is distinguishable from the subject application because Asahi did not submit an invention disclosure with drawings and other evidence of actual reduction to practice. Likewise, the court in In re Asahi/American Inc. did not evaluate the sufficiency of these types of materials to evidence a reduction to practice. Moreover, the Applicant respectfully submits that the Invention Disclosure and its drawings, in combination with the Declaration, are sufficient to establish actual reduction to practice of the Invention before the effective filing date of Jackson. Indeed, contrary to the assertion set forth in the Office Action, the Invention Disclosure submitted with the Declaration is more than mere “notebook” pages. Instead, the Invention Disclosure itself is a formalized corporate document that requires (and includes) date-recorded execution by each of the inventors along with a pair of attesting witnesses. In addition, the drawings accompanying the Invention Disclosure are not simple sketches that would typically be found on “notebook” pages. Rather, the drawings of the Invention Disclosure are computer-generated, with at least some of them being in an “engineering” form commonly used and referred to during manufacturing. As a corollary, the Invention Disclosure is more akin to the types of evidence enumerated in 37 CFR 1.131(b), as well as the evidence submitted by Asahi, than to mere “notebook” pages. Furthermore, as attested to in the Declaration, the Invention Disclosure also includes a “Date Constructed” that occurred prior to the effective filing date of Jackson. For at least the reasons set forth above, it is

respectfully submitted that the Declaration and Invention Disclosure are clearly sufficient to establish that the Invention had been constructed prior to the effective date of Jackson.

Moreover, as also attested to in the Declaration, the Invention Disclosure also provides a "Date First Tested" that occurred before the effective date of Jackson. Thus, it is submitted that the Declaration and Invention Disclosure establish an actual reduction to practice by showing that the Invention actually existed and worked for its intended purposed. The Applicant also notes that the Invention, similar to the restraint coupling claimed by Asahi and in accordance with In re Asahi/American Inc., is a simple device, the mere construction of which alone is sufficient to show that it worked for its intended purposed. Accordingly, it is respectfully submitted that the mere construction of the Invention, as established by the Declaration and Invention Disclosure, is sufficient to establish an actual reduction to practice of the Invention. As a corollary, removal of Jackson as prior art to the subject application is believed to be proper, and removal of Jackson as prior art to the subject application is respectfully requested.

The Office Action further indicates that factual evidence has not been supplied to establish diligence from just before the effective date of Jackson up to the priority date of the subject application. Since the Declaration and Invention Disclosure are believed to properly establish an actual reduction to practice of the Invention before the effective filing date of Jackson, the Applicant defers submitting any additional evidence to establish diligence at this time. However, it is noted that the period for which diligence must be established is only five and on-half months long, and the Applicant believes that additional information could be identified to account for the entire period. Thus, in the unanticipated event reliance on diligence is necessary, the Applicant hereby reserves the right to submit additional evidence establishing and supporting the same.

Arguments in Support of Patentability

In addition to claiming prior Invention in the United States under 37 C.F.R. §1.131, the Applicant also previously submitted arguments in support of patentability of the pending claims. On page 8 of the outstanding Office Action, under the heading "Response to Arguments," an assertion is made that "Applicant's arguments directed to the declaration filed 01/14/2009 have been fully considered but they are not persuasive, as described above in the 'Response to Amendments' section." However, there is no indication under this heading, or under the

“Response to Amendments” heading, that the Applicant’s arguments in support of patentability have been fully considered. Indeed, the content of pages 3-8 under the heading “Claim Rejections – 35 USC § 103” of the outstanding Office Action substantially corresponds to the content of pages 2-8 under the same heading of the Office Action dated June 26, 2008. Moreover, the comments under the “Response to Amendment” section of the outstanding Office Action deal exclusively with the Declaration. Thus, it does not appear that the Applicant’s previous arguments supporting patentability have been fully considered. In the absence of such consideration and a response to these arguments, it is submitted that the issues in this case have not been sufficiently developed to such an extent that the Applicant may readily judge the advisability of an appeal as required by Manual of Patent Examining Procedure §706.07. Accordingly, full consideration of the arguments set forth in the Applicant’s previous response, along with the following comments, is respectfully requested.

For the sake of efficiency and convenience, and to facilitate an expedient review of the same, the Applicant’s arguments in support of patentability are summarized below.

Independent Claim 1 and Dependent Claims 2-5, 7-8, 10-11, 12, 31 and 34-35

As indicated above, claims 1, 2, 4, 6, 10-11, 31 and 34-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Jackson in view of Miskew. Independent claim 1 recites, among other features and elements, “a second hook . . . comprising a second internal surface having a curved portion including a ridge extending along said curved portion in a direction from the first end to the second end” The outstanding Office Action indicates that Jackson fails to disclose this feature. (See page 5; line 16 to page 6, line 5). However, the Office Action asserts that “[i]t would have been obvious . . . to have substituted the thread mechanism disclosed by Jackson with the ridge mechanism disclosed by Miskew, in order to achieve the predictable result of providing stability to the construct.” (See page 6, lines 6-15). It is respectfully submitted that, when considering Jackson in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention as required by the MPEP §2141.02, those having skill in the art would not modify Jackson in the manner suggested by the Office Action.

Jackson discloses a cross member 5 that includes a pair of hooks 11 formed on opposite ends of a link 10. Each hook 11 includes a curved section 14 which has “an inner surface which is sized and shaped to closely contact and tightly abut against an outer surface 18 of a rod 4 in at least partially surrounding relation.” (See column 5, lines 23-36; emphasis added). Jackson also discloses a set screw 1 that includes a mounting segment 25 and a rod engaging segment 27 that engages the rod 4 to prevent the rod from rotating about its axis within rod receiving opening 20. (See column 5, lines 44-48 and 54; and column 6, line 5). Engagement between the segment 27 and the rod 4 urges a portion of the surface 18 of the rod 4 into frictional engagement with the inner surface 16 of the opening 20, which “. . . resists linear displacements of the rod 4 relative to the cross member 5, as well as angular or radial displacements”. (See column 6, lines 9-11; emphasis added). With regard to Miskew, this reference discloses an elongated threaded rod 72 which includes a plurality of hooks 74. Each of the hooks 74 includes “. . . a knife edge 78 inside the hook to achieve more secure hooking to the individual vertebra.” (See column 6, lines 34-37). Notably, the hook 74 is specifically configured to bite into and engage vertebral bone via the knife edge 78, and not to clampingly engage a spinal rod. As illustrated in Figure 6 of Miskew, a pair of linear segments angularly extends from the interior mid-portion of the curved section of the hook 74 toward one another and converge to define a sharp point that defines the knife edge 78. Moreover, as illustrated in Figure 5 of Miskew, the knife edge 78 extends beyond the interior portion of the curved section of hook 74.

When considering the emphasis Jackson places on the interaction and secure engagement between the set screw 1 and the rod 4, those skilled in the art would not substitute the set screw 1 for the knife edge 78, as suggested by the Office Action. Indeed, such substitution would eliminate some of the functional aspects provided by the set screw 1 which are repeatedly mentioned in Jackson. For example, substituting the set screw 1 of Jackson with the knife edge 78 would not resist/prevent rotation of the rod 4 within the rod receiving opening 20, as specifically taught by Jackson. Accordingly, those skilled in the art would be further lead away from the modification suggested by the Office Action.

Additionally, when considering Jackson in its entirety, those skilled in the art would not modify the connector 5 to include the knife edge 78 in combination with the set screw 1. For example, if Jackson were modified to include the knife edge 78 disclosed by Miskew, the inner

section 16 of the curved portion 14 of the hook 11 would no longer be shaped to closely contact and tightly abut against the outer surface 18 of rod 4 (as explicitly taught by Jackson and discussed above). Instead, only the pointed end of the knife edge 78 would contact the outer surface 18 of the rod 4, which would lead to instability and non-secure engagement between the rod and the connector hook. As a corollary, the possibility of the rod 4 being angularly displaced relative to the cross member 5, an occurrence Jackson specifically teaches is undesirable (see above), would be increased. Therefore, the Applicant respectfully submits that Jackson clearly teaches away from adding a knife edge 78 to an inner surface of the connector hook, and those skilled in the art would be dissuaded from doing so. Furthermore, as indicated above, the hook 74 of Miskew is specifically configured to bite into and engage vertebral bone via the knife edge 78, and not to clampingly engage a spinal rod.

In view of the foregoing, the Applicant respectfully submits that a *prima facie* case of obviousness has not been established with regard to independent claim 1. Accordingly, withdrawal of the rejection of independent claim 1 in view of the Jackson/Miskew combination and allowance of same are respectfully requested.

Each of claims 2, 4, 6 and 10-11, 31 and 34-35 depends from independent base claim 1 or an intervening claim, and is patentable over the Jackson/Miskew combination for at least the reasons supporting the patentability of independent base claim 1, although further reasons support the patentability of these claims. For example, claim 34 recites “wherein said curved portion curves in a second direction extending obliquely to and intersecting said ridge” and claim 35 further recites “wherein said curved portion curves in said second direction from a first lateral edge of said second hook to a second lateral edge of said second hook.” As will be discussed in greater detail below with respect to independent claim 13, Miskew does not disclose a curved portion that curves in more than one direction, but instead includes a pointed knife edge 78 defined by linear surfaces that converge at a point. Furthermore, as illustrated in Figure 6 of Miskew, the linear segments that define the knife edge 78 do not extend from a first lateral edge to a second lateral edge of hook 74. Instead, these linear segments are positioned in the middle portion of the hook 74. Accordingly, the subject matter of claims 34 and 35 has not been accounted for and a *prima facie* case of obviousness of these claims has not been established for these reasons as well.

Claims 3 and 5 depend from independent base claim 1 or an intervening claim, and stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew/Lombardo combination. The addition of Lombardo does not overcome the above-mentioned deficiencies of the Jackson/Miskew combination with respect to the rejection of independent claim 1. Accordingly, claims 3 and 5 are patentable over the Jackson/Miskew/Lombardo combination for at least the reasons supporting the patentability of independent claim 1.

Claims 7 and 8 depend from independent base claim 1 or an intervening claim, and stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew combination in further view of the '523 patent. The '523 patent does not overcome the above-mentioned deficiencies of the Jackson/Miskew combination with respect to the rejection of independent claim 1. Accordingly, claims 7 and 8 are patentable over this combination of references for at least the reasons supporting the patentability of independent claim 1.

Claim 12 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew combination. Claim 12 is directed to a method of treating a spinal deformity that includes, among other features, "... providing an apparatus according to claim 1". For at least the reasons discussed above in support of the patentability of independent claim 1, the Applicant submits that claim 12 is patentable for at least these reasons as well.

Independent Claim 13 and Dependent Claims 14-18, 21, 32 and 36

Claims 13-16, 21, 32 and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew combination. Independent claim 13 is directed to an apparatus and recites, among other elements and features, "a second hook . . . comprising a second internal surface wherein the second internal surface curves both in a first direction from the shaft to the second end and in a second direction oblique to the first direction, wherein said curves in said first and second directions are overlapping and intersecting" For reasons similar to those discussed above in support of the patentability of independent claim 1, those skilled in the art would not modify Jackson in view of Miskew to arrive at the invention recited in independent claim 13.

However, further reasons support the patentability of independent claim 13. With regard to Miskew, as indicated above, a pair of linear segments angularly extends from the interior

portion of the curved section of hook 74 toward each other to a sharp point that defines a knife edge 78. Contrary to the assertion set forth on page 6 of the Office Action, the linear segments of knife edge 78 do not “. . . produce curves that arch in an oblique direction relative to the curve of the hook . . .”. Indeed, as clearly shown in Figure 6 of Miskew, the linear edges defining the pointed knife edge 78 are not in any way “curved” and do not “arch” in any direction. As a corollary, the Jackson/Miskew combination fails to disclose a second internal surface that curves both in a first direction from the shaft to the second end and in a second direction oblique to the first direction, as recited in independent claim 13.

In view of the foregoing, independent claim 13 is submitted to be patentable over the cited references, and allowance of same is respectfully requested. Each of claims 14-18, 21, 32 and 36 depends from independent base claim 13 or an intervening claim and is patentable over the Jackson/Miskew combination for at least the reasons supporting the patentability of independent base claim 13, although further reasons support the patentability of these claims. For example, claim 36 recites “wherein said second internal surface curves in said second direction from a first lateral edge of said second hook to a second lateral edge of said second hook.” For reasons similar to those discussed above with respect to claims 34 and 35, the subject matter of claim 36 has not been accounted for by the cited references.

Claims 17 and 18 depend from independent base claim 13 or an intervening claim and stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew combination in further view of the ‘523 patent. The ‘523 patent does not overcome the above-mentioned deficiencies of the Jackson/Miskew combination with respect to the rejection of independent claim 13. Accordingly, claims 17 and 18 are patentable over this combination of references for at least the reasons supporting the patentability of independent base claim 13.

Independent Claim 33 and Dependent Claims 37 and 38

As indicated above, it is believed that independent claim 33 also stands rejected in view of the Jackson/Miskew combination. Independent claim 33 is directed to an apparatus and recites, among other features and elements, “a second hook portion . . . comprising a second internal surface having a curved portion including a saddle extending along said curved portion in a direction from said first end to said second end . . .” For at least the reasons discussed

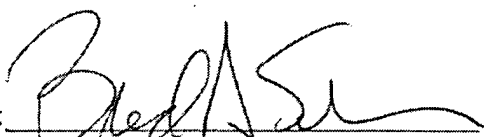
above with respect to independent claims 1 and 13, it is respectfully submitted that those skilled in the art would not modify Jackson in view of Miskew to arrive at the invention recited in independent claim 33. Notably, independent claim 33 recites “a curved portion” which includes “a saddle extending along said curved portion in a direction from said first end to said second end”. The Applicant submits that the pointed knife edge 78 fails to satisfy these features.

In view of the foregoing, independent claim 33 is submitted to be patentable over the cited references, and allowance of same is respectfully requested. Each of claims 37 and 38 depends from independent base claim 33 or an intervening claim and is patentable over the cited combination of references for at least the reasons supporting the patentability of independent base claim 33, although further reasons support the patentability of these claims. For example, claims 37 and 38 recite subject matter similar to that recited in claims 34 and 35 and a further patentable for reasons similar to those discussed above with respect to claims 35 and 35.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance with pending claims 1-5, 7-8, 10-18, 21 and 31-38. Reconsideration of the present application is respectfully requested. Timely action towards a Notice of Allowance is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the present application.

Respectfully submitted,

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